

Attorney Docket No.: DEX-0247  
Inventors: Sun et al.  
Serial No.: 10/082,828  
Filing Date: October 29, 2001  
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#### REMARKS

Claims 1-17 are pending in the instant patent application. Claims 6 and 9-17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5 and 7-8 have been rejected. Claim 1 has been amended. Support for the amendments is provided in the specification at page 13, line 28 through page 16, line 20, pages 31 through 40 and Example 1 beginning at page 116. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed May 1, 2003. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled nonelected claims 6 and 9-17. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

#### II. Objection to Specification and Claims

The disclosure has been objected to because it contains embedded hyperlinks and/or other forms of browser executable

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code. Accordingly, in an earnest effort to advance the prosecution of this case, the specification has been amended to inactivate all embedded hyperlinks by removing "http" and "www" and simply referring to the world wide web. No new matter is added by this amendment and entry is respectfully requested.

The claims have been objected to as including subject matter which had been non-elected due to the Restriction Requirement. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the elected subject matter namely SEQ ID NO:75 or the amino acid sequence encoded thereby, SEQ ID NO:207. No new matter is added by these amendments.

Withdrawal of the objections to the specification and claims is respectfully requested in light of the amendments thereto.

**III. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, second paragraph**

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner suggests that the term "selectively" in claim 1, line 6, is vague and indefinite because

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it is unclear what criteria are being used to determine that a nucleic acid molecule selectively hybridizes to another.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have deleted the term "selectively" from the claims. Instead, Applicants have amended the claims to state that the nucleic acid molecule hybridizes under stringent conditions. Support for this amendment can be found in the specification at page 14, line 16 through page 16, line 30 wherein detailed teachings of what is meant by stringent hybridization are provided. The claim as amended is therefore clear and definite when read in light of the teachings of the specification as required by MPEP § 2173.03.

The phrase "at least 60% sequence identity" in claim 1 at line 8 is also suggested to be vague and indefinite because it is unclear what criteria are being used to determine that one nucleic acid sequence has "at least 60% sequence identity" to another. Applicants respectfully traverse this rejection.

As mandated by MPEP § 2173.02; definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application; the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at

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the time the invention was made. Methods for determining percent sequence identity are described in detail in the specification at pages 13-14 of the instant specification. Further as made clear in this section of the application, methods for determining sequence identity are well known in the art and utilize commercially available software programs. Accordingly, how to determine a % sequence identity is clear and definite when read in light of the teachings of the specification and what is well known in the art. Thus, further clarification in the claims is not required. See MPEP § 2173.03.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested in light of the amendments to the claims and the above remarks.

**IV. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph**

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. Claims 1-5, 7 and 8 have also been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence. Specifically, the Examiner suggests that no data indicating specificity of the elected sequence, SEQ ID NO:75, are provided.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the Examiner's assertion of no data of specificity for SEQ ID NO:75 being provided is incorrect. Example 1 beginning at page 116 of the specification provides detailed teachings of experiments wherein SEQ ID NO:75 was demonstrated to be a CLASP 2 marker, which as taught at page 117, lines 18-22 is detectable only in breast cancer tissue. These data are clearly demonstrative of SEQ ID NO:75, as well as SEQ ID NO:207, the amino acid sequence encoded thereby, being useful diagnostic markers for breast cancer tissue.

Accordingly, since the basis for the Examiner's rejections under 35 U.S.C. § 101 and 112, first paragraph, is incorrect, withdrawal of these rejections is respectfully requested.

V. Rejection of Claims 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed had possession of the claimed invention. The Examiner suggests that the specification provides insufficient written description to support the genus encompassed by the claim which is directed to sequences that selectively hybridize to a sequence of SEQ ID NO:75 and a sequence having at least 60% identity to a sequence of SEQ ID NO:75.

Applicants respectfully traverse this rejection.

The written description requirement of 35 U.S.C. § 112, first paragraph, as set forth in MPEP § 2163.02 requires that the specification set forth definitive structural features of the claimed polynucleotides so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. Claim 1, now amended to be drawn to a nucleic acid molecule encoding an amino acid of SEQ ID NO:207, comprising SEQ ID NO:75, hybridizing under stringent conditions to a nucleic acid molecule of SEQ ID NO:75 or exhibiting 85% sequence identity to SEQ ID NO:75 clearly sets forth such definitive structural features.

Further, Applicants have amended claim 1 in accordance with teachings throughout the specification and in particular at page

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31-36 and Example 1 to state that the nucleic acid molecule is a breast specific nucleic acid, thus providing a further functional characteristic as well by which one of skill in the art can predictably identify the encompassed molecules.

MPEP 2163.02 also requires that the specification must show that applicant was in possession of the claimed invention. Possession of a nucleic acid molecule encoding an amino acid sequence of SEQ ID NO:207 or comprising SEQ ID NO:75 as set forth in parts (a) and (b) of claim 1 is clearly evidenced by teachings in the Sequence Listing of the instant application and Example 1 beginning at page 116 wherein expression of this nucleic acid molecule is demonstrated to be breast cancer specific. Part (c) of claim 1 has been amended and is now drawn to a nucleic acid molecule that hybridizes to SEQ ID NO:75 under stringent hybridization conditions. Applicants' possession of this invention is clearly evidenced by teachings at pages 14 through 17 wherein a detailed description regarding determining nucleic acid molecules which hybridize under stringent conditions is set forth. Part (d) of claim 1 has also been amended to be drawn to a nucleic acid molecule that has at least 85% sequence identity to SEQ ID NO:75 in accordance with teachings at page 32, line 20. Nucleic acid molecules with at least 85% sequence identity are

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thus described at page 32 of the specification and detailed methodologies for determining percent sequence identity are taught at pages 13 through 14 thus evidencing Applicants' possession of this invention.

Accordingly, the instant claims and specification meet the written description requirements of 35 U.S.C. 112, first paragraph as set forth in MPEP 2163.02. Therefore, withdrawal of this rejection is respectfully requested in light of the amendments to the claims and the above remarks.

**VI. Rejection of Claims 1, 3-5, 7 and 8 under 35 U.S.C. § 102(a)**

Claims 1, 3-5, 7 and 8 have been rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Birren et al. (May 2000). The Examiner suggests that Birren et al. discloses a nucleic acid molecule that has at least 60% sequence identity to the nucleic acid molecule of SEQ ID NO:75.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims in accordance with teachings at page 32, line 20 to state that the nucleic acid molecule has 85% sequence identity to SEQ ID NO:75. The sequence comparison of Birren et al. and the SEQ ID NO:75 of the instant application provided by the Examiner shows at most 81.6% sequence identity. Thus, this reference does not anticipate the



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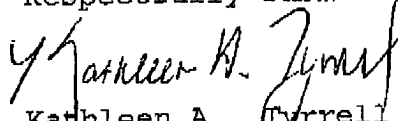
claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(a) is therefore respectfully requested.

#### VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Kathleen A. Tyrrell  
Registration No. 38,350

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LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515